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EXAMINER

MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,644

Applicant(s)

BITTERHOF, ANDREAS

Examiner

Patricia C. Mallari

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 4-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 recites "means for facilitating direct impingement of a portion of the bodily fluid passed by the user into contact with the analysis means separate from contact with the absorbent element" on lines 5-7 of the claim and "means for disposing the analysis device on the absorbent element" on lines 7-8 of the claim. While the applicant discloses that analysis device "is disposed at a place on the hygiene item which can be impinged upon by the bodily fluid to be analyzed" (paragraph [0010] of the instant application), the specification as originally filed fails to teach a corresponding means (structure or instrument) for doing so. Similarly, the applicant's disclosure teaches that the analysis device "is disposed on the hygiene item" (paragraph [0010] of the instant application), the applicant still fails to teach a means (structure or instrument) for doing so. Also, claim 5 recites the limitation "wherein the edges of the insert are folded over on an upper side of the analysis device". However, the specification as originally filed fails to provide adequate support for this limitation. The specification states that "Edges 12 of the insert 2, which connect to the sidewalls 10, are folded over

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to the inside on one top side 12" in paragraph [0019] but fails to state that the edges are folded over on an upper side of the analysis device 4. Figures 1 and 3 of the instant application also fail to show the edges 12 being folded over on an upper side of analysis device 4.

Furthermore, the addition of language into the applicant's specification to support the recited limitations in either claim 1 or claim 5 would result in an objection under 35 U.S.C. 132 as an introduction of new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 4-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites, "the separating means is configured as an insert in the absorbent element and contains the analysis device". Paragraph [0012] on page 4 of the applicant's specification defines "insert" as "an area of the hygiene item separated by the separating means from the remainder of the absorbent element". It is unclear how the separating means is an area separated by itself. The specification describes the separating means as forming part of the insert rather than configured as the insert itself (p. 4, paragraph [0012], p.5, paragraph [0018], figs. 1 and 3 of the instant specification), and for the purposes of this examination, the claim language will be interpreted as such.

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However, should the applicant intend either this description or another description entirely, the claims, in either case, should be amended to clearly reflect that intention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6-9, and 11-15 are rejected under 35 U.S.C. 102(e) as being anticipate by US Patent No. 6,126,597 to Smith et al. Smith teaches a hygiene item comprising an absorbent element 12 (col. 4, lines 26-31) configured to absorb and retain bodily fluid passed by a user, wherein commonly worn panties are absorbent and capable of retaining at least some bodily fluid that may be passed by a user. An analysis device 34 includes means for analyzing at least one characteristic (pH) of bodily fluid passed by the user (col. 5, line 66-col. 6, line 10). Means 26 facilitates direct impingement of a portion of the bodily fluid passed by the user into contact with the analysis means separate form contact with the absorbent element (figs. 1-2; col. 4, lines 50-53). Means 10, as well as mere placement of the analysis device 34, disposes the analysis device 34 on the absorbent element 12 (fig. 3; col. 4, lines 33-36; col. 6, lines 42-44). Means 26, 28 separates the bodily fluid in the analysis device 34 from the absorbent element 12 in an essentially fluid tight manner, wherein means 28 may be

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composed of a polyethylene film (figs. 2 & 3; col. 5, lines 1-4), which is liquid impervious (See col. 3, lines 51-52 of SIR H1298 to Ahr et al. for a teaching of polyethylene as liquid impervious). Since part of the separating means 26, 28 is liquid impervious and placed between analysis device 34 and absorbent means 12, it is also configured to retain any bodily fluid that has penetrated to the absorbent element 12 away from the analysis device 34 thereby preventing bodily fluid contaminated by the absorbent element 34 from falsifying an analysis of the analysis device 34.

As to the language "single use" on line 1 of claim 1 and "disposable on line 2 of claim 1", the applicant should note that this is merely "intended use" language which cannot be relied upon to define over Smith et al., since the reference teaches all of the claimed elements and their recited relationships. See *Ex parte Masham* 2 USPQ 2nd 1647. The absorbent element 12 of Smith et al. is certainly capable of being used once and/or thrown away if a user so desires, and the language "single use" or "disposable" fails to impart any structural difference between the invention of claim 1 and that described by Smith et al.

Regarding claims 2, 6-9, and 11-14, the separating means 26, 28 is part of an insert 10, wherein the insert 10 which is an area of the hygiene item separated by the separating means 26, 28 from the remainder of the absorbent element 12 (figs. 1 and 2).

With further regard to claim 6, the insert 10 is delineated by the separating means 26, 28, part of which comprises a fluid-impermeable film (col. 5, lines 1-5).

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With further regard to claim 7, the insert 1 is essentially flush-mounted with the upper side of the absorbent element 12 facing the body (figs. 1-3).

With further regard to claims 8, 9, and 15 the analysis means 34 is positioned up against one side 28 of the separating means 26, 28 (figs. 2 & 3). With further regard to claims 9 and 15, a side 26 of the separating means 26, 28, against which the analysis device 34 is disposed, allows visual reading of a color change in the analysis means 45 (col. 5, line 66-col. 6, line 10), wherein the analysis means 34 and the side 26 of the separating means 26, 28 function as a visual display unit.

With further regard to claims 11 and 12, the separating means 26, 28 containing the analysis device 34 is separable from the hygiene item 12 and is detachably fastened to the hygiene item 12 by means of an adhesive (col. 6, lines 41-44).

With further regard to claim 13, the insert 10 containing the analysis device 34 has a fluid absorbing and transport layer which transfer the bodily fluid to the analysis device, wherein the fluid absorbing and transport layer comprises cellulose fibers (col. 5, lines 16-26).

With further regard to claim 15, the applicant should note that the limitations regarding the single-use hygiene item (i.e. "the single-use hygiene item including . . .") fail to bear any patentable weight since the claim does not positively claim the single-use hygiene item.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith, as applied to claims 1, 2, 6-9, and 11-15 above, and further in view of and further in view of US Patent No. 4,114,621 to Mims, Jr. Smith fails to describe the insert having sidewalls or the edges of the insert being folded over on an upper side. Mims, Jr. teaches an insert 11, designed to be placed in an absorbent element 10, similar to that of Smith et al. The insert features sidewalls 45 extending up on a side facing the body (Col. 3, lines 37-38. figs 4 and 6 of Mims, Jr.) Figure 6 shows these sidewalls being formed by the edges of surface 34 of the insert 11 being folded over on an upper side. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the sidewalls of Mims, Jr. with the item of Smith et al. in order to further reduce the chance of leakage from the insert to the absorbent element (col. 3, lines 37-38 of Mims, Jr.)

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of Mims, Jr., as applied to claim 4 above. Smith, as modified, fails to teach the edges of the insert being folded over on an upper side of the analysis device. However, it appears that the folded edges of Smith in view of Mims, Jr. would be folded over an upper side of the analysis device if the folds were large enough. The applicant has not disclosed that the size of the folded edges solves any stated problem or serve any particular purpose. Moreover, it appears that the hygiene item would perform equally well with folded edges of any reasonable size. Accordingly, the recitation that the edges

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are folded over on an upper side of the analysis device is deemed to be a design consideration which fails to patentably distinguish over the prior art of Smith in view of Mims, Jr.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. in view of Todd et al. While Smith et al. teaches an upper layer of the separating means 26 allowing the color of the display unit 36 to be visualized by the wearer through the layer of the separating means 26, the reference fails to describe layer 26 as being transparent. However, Todd discloses an analysis device 10 having a display unit 24 providing a color change as an indication of analysis results, the display unit is immediately adjacent to a transparent outer layer of separating means 14 (figs. 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a transparent layer as the upper side of the separating means of Smith et al., since Smith teaches an upper layer that allows visualization of the display unit through the separating means and Todd et al. describes that a transparent material would be suitable for such a visualization.

Response to Arguments

Applicant's arguments filed 9/20/04 have been fully considered but they are not persuasive.

The applicant states that the undergarment 12 of Smith et al. is not configured to absorb and readily retain bodily fluid passed by the user. However, Smith teaches that the undergarment 12 is of the type commonly worn by many women and well-known as a panty (col. 4, lines 29-31). While Smith does not explicitly recite that the

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undergarment is used to absorb and retain bodily fluid passed by a user, such an undergarment is made of a cloth material and is inherently capable of absorbing and retaining at least some bodily fluid which a user may pass to some extent. The statement in Smith describing the use of article 10 as an absorbent pad and the statement that the article 10 may function as a feminine napkin, pad, panty liner, or shield fail to detract from the undergarment 12 being absorbent itself. Additionally, the applicant should note that the phrase "bodily fluid passed by the user" encompasses *any* fluid from the body of the user (e.g. sweat, oil) and is not limited to bodily fluid passed by only a particular body portion. Thus, the Smith reference as a whole teaches a hygiene item having an absorbent element 12 and an analysis device 34 configured to accept direct impingement of bodily fluids separate from fluid absorbed and retained in the absorbent element 12 (figs. 1-3).

The applicant also argues that Smith lacks teaching of the combination of panty 12 and article 10 as a distinct element because they are disclosed as separate elements. However, the applicant's invention, while disclosed as composed of many distinct parts, is considered by the applicant to be an "item". Further, many items can be broken down into distinct parts, such as distinct pages making up a book, wherein a book is considered to be an "item" in and of itself. Similarly, the parts panty 12 and article 10, can be considered together as a distinct item, particularly when, as shown in figure 3 of Smith, article 10 is adhere to the panty 12. Neither the term "item" nor any other language in claim 1 requires the analysis device and absorbent element to be

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inseparable parts of a distinct element. If the applicant wishes to impart such a quality on the claimed invention, the claim language should be amended to reflect it.

The applicant contends that Smith lacks a teaching or suggesting that separating means isolates a further absorbent layer from analyzing means 34, but it is unclear what the applicant intends to prove with this argument. None of the claims of the present application address the separating means isolating a second absorbent layer from the analyzing means, and the rejection presented above already delineates the relationship between the separating means and the first absorbent layer or panty 12.

The applicant should refer to the rejection under 35 U.S.C. 112, 1st paragraph, presented above, in reference to the argument that Smith lacks any teaching direct to the means for disposing the analysis device on an absorbent element. The phrase "means for" invokes 35 U.S.C. 112, 6th paragraph, wherein a means plus function limitation is construed to cover the corresponding structure described in the specification and equivalents thereof. See MPEP §2181. Lacking a clearly corresponding structure in the specification, the means have been given their broadest reasonable interpretation as claimed. Therefore, the inclusion of the analysis device 34 of Smith into an article 10 and the adhesive 36 on the bottom of the article 10 allows the device 34 to be disposed on an absorbent element 12 (col. 4, lines 29-36; col. 6, lines 42-44; figs. 1-3 of Smith). Therefore, Smith clearly teaches a means 10, 36 for disposing the analysis device on an absorbent element.

With regard to the use of the term "insert", the applicant should consider the rejection of claim 2 under 35 U.S.C. 112, 2nd paragraph presented above and the

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interpretation the claim language has been given for the purposes of this examination. Because the language on p. 4, paragraph [0012] of the applicant's specification clearly states, "The term 'insert' is to be understood as . . .", the definition provided therein is considered the definition of the term "insert" as used in the claims. No other description of the insert in the specification is accompanied by such language, and, therefore, no other description in the specification is considered to define the term "insert" as used in the claims. Smith's disclosure of the insert 10 as possibly being worn like a sanitary napkin or pad fails to show how the insert 10 is not an area of the hygiene item separated by the separating means 26, 28 from the remainder of the absorbent element 12.

The applicant argues, with regard to claim 7, that Smith fails to teach or suggest that the analysis means is positioned against one side of the separating means. However, it is claim 8, not claim 7 that recites this limitation. Figures 2 and 3 of Smith show the analysis means 34 being essentially flush mounted against one side 26 of the separating means 26, 28. Smith's disclosure of the side 26 of the separating means 26, 28 allowing the user to visualize a color change in the analysis means 34 is in no way contrary to Smith's teaching of the analysis means 34 being positioned against one side 26 of the separating means 26, 28. The applicant further contends that the Smith reference fails to teach or suggest the applicant's invention as set forth in claim 9. As the applicant points out, Smith describes in col. 5, line 65-col. 6, line 10 that one side 26 of the separating means 26, 28 allows the user to visualize a color change in the

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analysis means 34, such that the one side 26 of the separating means 26, 28 and the analysis means 34 function together as a visual display unit.

With regard to claims 11 and 12, the applicant asserts that because the Smith reference states that the user does not have to disassemble the article to verify color, Smith fails to teach that the analysis means is not separable from the hygiene item. However, a statement that disassembly is not *required* is not the same as disclosure that disassembly is not *possible*. Furthermore, Smith shows that the analysis device 34 is separable from the hygiene item by means of the adhesive strip 26 used to removably attach the insert 10 to the absorbent element 12 (col. 6, lines 42-45 of Smith). In response to the applicant's repeated statement that the examiner has failed to demonstrated the undergarment is an absorbent element that retains bodily fluid, the applicant is once again directed to the examiner's statements above regarding undergarments and their capability of absorbing bodily fluids.

With regard to claim 15, the applicant argues that Smith fails to teach or suggest a visual display unit having measuring means associated therewith for measuring the composition of bodily fluids introduced therein or to teach or suggest an analysis device that can be maintained in separate fluid-tight contact with a suitable single-use hygiene item. The applicant should refer to the rejections set forth above as to how Smith teaches these limitations, keeping in mind that the pH of a substance is a measure of the composition of that substance. The applicant's arguments with respect to the rejection under 35 U.S.C. 103(a) over Smith in view of Todd are moot in light of the new grounds of rejection presented above under 35 U.S.C. 102(e) over Smith.

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In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is the combination of Smith with Mims, Jr. that teaches the device of claims 4 and 5 wherein the absorbent element isolated from the analysis device. Specifically, Mims, Jr. is relied upon to teach an insert having sidewalls or folded edges. Properties of the chemically treated wick 40 of Mims, Jr. are irrelevant to the combination. The applicant should also note the rejection of claim 5 under 35 U.S.C. 112, 1st paragraph and the new grounds of rejection of claim 5 presented above.

The applicant argues that claim 10 is not taught, anticipated, or rendered obvious by the cited references because claim 10 depends either directly or indirectly from claim 1 to contain all the limitations found therein. The examiner has explained above how the Smith reference anticipates claim 1, and the rejection presented above under 35 U.S.C. 103(a) shows how the invention of claim 10 is unpatentable over Smith in view of Todd.

Therefore, claims 1, 2, and 4-15 stand rejected as described above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

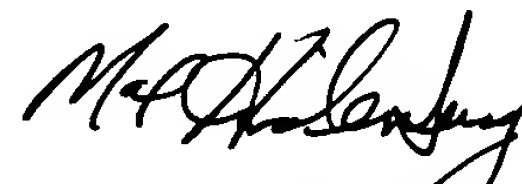
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patricia Mallari
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